

EFFECTS OF FLEXIBLE VISITS ON THE PREVENTION AND TREATMENT OF DELIRIUM IN INTENSIVE CARE: A SYSTEMATIC REVIEW PROTOCOL**EFFECTOS DE LAS VISITAS FLEXIBLES EN LA PREVENCIÓN Y EL TRATAMIENTO DEL DELIRIO EN CUIDADOS INTENSIVOS: UN PROTOCOLO DE REVISIÓN SISTEMÁTICA****EFEITOS DA FLEXIBILIZAÇÃO DE VISITAS NA PREVENÇÃO E TRATAMENTO DO DELIRIUM EM TERAPIA INTENSIVA: PROTOCOLO DE REVISÃO SISTEMÁTICA**¹Roberta Garcia Gomes²João Vitor Andrade³Mariane Inaraí Alves⁴Juliana Cristina Martins de Souza⁵Priscila Yoshida Machado Ferreira⁶Patrícia Scotini Freitas⁷Namie Okino Sawada¹Doutoranda em Enfermagem.

Universidade Federal de Alfenas,

Alfenas - MG, Brazil. ORCID:

<https://orcid.org/0000-0002-0277-4371>²Doutorando em Enfermagem.

Universidade Federal de Alfenas,

Alfenas - MG, Brazil. ORCID:

[https://orcid.org/0000-0003-3729-](https://orcid.org/0000-0003-3729-501X)

501X

³Doutoranda em Enfermagem.

Universidade Federal de Alfenas,

Alfenas - MG, Brazil. ORCID:

<https://orcid.org/0000-0001-6792-1398>⁴Doutoranda em Enfermagem.

Universidade Federal de Alfenas,

Alfenas - MG, Brazil. ORCID:

<https://orcid.org/0000-0002-1941-2262>⁵Doutoranda em Enfermagem.

Universidade Federal de Alfenas,

Alfenas - MG, Brazil. ORCID:

<https://orcid.org/0000-0001-8902-9173>⁶Doutora em Enfermagem. Docente

Permanente do Programa de Pós-

Graduação em Enfermagem.

Universidade Federal de Alfenas,

Alfenas - MG, Brazil. ORCID:

<https://orcid.org/0000-0002-8270-8955>⁷Doutora em Enfermagem.

Coordenadora do Programa de Pós-

Graduação em Enfermagem.

Universidade Federal de Alfenas-

UNIFAL. Universidade Federal de

Alfenas, Alfenas - MG, Brazil.

ORCID: [https://orcid.org/0000-0002-](https://orcid.org/0000-0002-1874-3481)

1874-3481

Corresponding Author**João Vitor Andrade**

Rua Gabriel Monteiro da Silva, 700,

Centro, Alfenas, MG, Brazil. CEP

37.130-001. Phone: +55(35) 3701-

9471, e-mail: jvma100@gmail.com.**Submission:** 23-02-2025**Approval:** 30-09-2025**ABSTRACT**

Objective: To evaluate the effects of the flexible visit on the prevention and treatment of delirium in Intensive Care Units (ICU). **Method:** Systematic review protocol drawn up according to the guidelines of the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) and registered with the International Prospective Register of Systematic Reviews (PROSPERO). The review will follow nine methodological stages: formulation of the research question, definition of inclusion and exclusion criteria, development of the search strategy, selection and evaluation of studies, extraction and synthesis of data, evaluation of the quality of the evidence and dissemination of the results. The search will be carried out in relevant databases, using descriptors such as Critical Care, Intensive Care Units, Critical Illness, Visitors to Patients, Caregivers, Delirium and their correspondents in Portuguese and Spanish, as well as related synonyms. Experimental and quasi-experimental studies will be included. Selection will be managed by the Rayyan web application. The risk of bias will be assessed using the Cochrane Collaboration Risk of Bias 2 tool, and the quality of the evidence will be classified according to the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) system. If the included studies meet the necessary requirements for meta-analysis, this will be conducted to determine the effect of the intervention.

Keywords: Delirium; Intensive Care Units; Visitors to Patients; Disease Prevention; Social Interaction.

RESUMEN

Objetivo: Evaluar los efectos de la visita flexible en la prevención y tratamiento del delirium en las Unidades de Cuidados Intensivos (UCI). **Método:** Protocolo de revisión sistemática elaborado según las directrices del Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) e inscrito en el Registro Prospectivo Internacional de Revisiones Sistemáticas (PROSPERO). La revisión seguirá nueve etapas metodológicas: formulación de la pregunta de investigación, definición de los criterios de inclusión y exclusión, desarrollo de la estrategia de búsqueda, selección y evaluación de los estudios, extracción y síntesis de los datos, evaluación de la calidad de la evidencia y difusión de los resultados. La búsqueda se realizará en bases de datos relevantes, utilizando descriptores como Critical Care, Intensive Care Units, Critical Illness, Visitors to Patients, Caregivers, Delirium y sus correspondientes en portugués y español, así como sinónimos relacionados. Se incluirán estudios experimentales y cuasi experimentales. La selección se gestionará mediante la aplicación web Rayyan. El riesgo de sesgo se evaluará mediante la herramienta Risk of Bias 2 de la Colaboración Cochrane, y la calidad de la evidencia se calificará mediante el sistema Grading of Recommendations, Assessment, Development and Evaluation (GRADE). Si los estudios incluidos cumplen los requisitos necesarios para realizar el metaanálisis, este se llevará a cabo para determinar el efecto de la intervención.

Palabras clave: Delirio; Unidades de Cuidados Intensivos; Visitas a Pacientes; Prevención de Enfermedades; Interacción Social.

RESUMO

Objetivo: Avaliar os efeitos da visita flexível na prevenção e tratamento do delirium em Unidades de Terapia Intensiva (UTI). **Método:** Protocolo de revisão sistemática elaborado conforme as diretrizes do Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) e registrado na International Prospective Register of Systematic Reviews (PROSPERO). A revisão seguirá nove etapas metodológicas: formulação da questão de pesquisa, definição de critérios de inclusão e exclusão, desenvolvimento da estratégia de busca, seleção e avaliação dos estudos, extração e síntese dos dados, avaliação da qualidade da evidência e disseminação dos resultados. A busca será realizada em bases de dados relevantes, utilizando descritores como Critical Care, Intensive Care Units, Critical Illness, Visitors to Patients, Caregivers, Delirium e seus correspondentes em português e espanhol, além de sinônimos relacionados. Serão incluídos estudos experimentais e quase-experimentais. A seleção será gerenciada pelo aplicativo web Rayyan. O risco de viés será avaliado com a ferramenta Cochrane Collaboration Risk of Bias 2, e a qualidade da evidência será classificada segundo o sistema Grading of Recommendations, Assessment, Development and Evaluation (GRADE). Se os estudos incluídos cumprirem os requisitos necessários para a realização da metanálise, esta será conduzida para determinar o efeito da intervenção.

Palavras-chave: Delirium; Unidades de Terapia Intensiva; Visitas a Pacientes; Prevenção de Doenças; Interação Social.



INTRODUCTION

Intensive Care Units (ICUs), designed for the care of critically ill patients with potential risk of death and requiring uninterrupted and interdisciplinary care, are characterized as high-complexity care settings. ICUs have a differentiated physical structure, high maintenance costs, high technological density, and demand a qualified multidisciplinary team⁽¹⁻²⁾.

In ICUs, distinct treatments are carried out, each intended to meet patients' needs. These treatments aim to restore patients' vital functions⁽¹⁾. However, alongside the care provided by the team, patients become more vulnerable due to altered levels of consciousness, need for ventilatory support, use of vasoactive drugs or sedatives, hemodynamic instability, enteral or parenteral nutrition, recurrence of invasive procedures, prolonged movement restrictions, among other conditions⁽³⁾.

Among the possible complications that may occur in ICUs, one of the main conditions that worsens patients' situations is delirium⁽⁴⁾. According to the international literature, delirium, or acute brain dysfunction, occurs in approximately 15% to 57% of hospitalized patients, being associated with in-hospital mortality ranging from 25% to 33%⁽⁵⁾.

Described by the Diagnostic and Statistical Manual of Mental Disorders as an acute confusional state characterized by fluctuating mental status, inattention, and altered consciousness or disorganized thinking, delirium affects more than 35% of all critically ill

patients⁽¹⁾. It is reported that patients undergoing mechanical ventilation are particularly more susceptible to the condition, with rates reaching up to 80%. This occurs because sedative, analgesic, and hypnotic drugs, frequently used in ICUs to provide patient comfort, have a deliriogenic effect⁽⁶⁾.

A study conducted in the United States revealed that the daily care costs of a patient with delirium increased by approximately US\$600 per day and US\$18,000 per month. This increase results from the use of additional services, including bed-related expenses, laboratory costs and diagnostic work-up, pharmaceutical expenses, among others⁽⁷⁾.

At the national level in the United States, total healthcare expenditures associated with delirium range from US\$38 to US\$152 billion per year^(6,8). Therefore, rapid identification and effective intervention by the multidisciplinary ICU team are required to reduce or eliminate patient harm and prevent poor prognoses⁽⁹⁾. No Brazilian data on the financial impacts of delirium were found; however, based on the evidence presented, delirium is understood to be an important public health problem.

Furthermore, in the treatment of delirium, both pharmacological and non-pharmacological interventions are employed. Among the latter, flexible visitation stands out as a potentially effective measure. Studies have emphasized that the presence of close individuals (family members, friends, etc.) does not cause stress to the patient⁽¹⁰⁾ and is associated with clinical improvement and reduced ICU length of stay⁽¹¹⁾.

Thus, flexible hospital visitation is valued not only for the direct benefits it provides to patients but also for its alignment with the ABCDEF Bundle, a set of multidisciplinary interventions aimed at improving clinical outcomes and the patient experience in the ICU⁽¹²⁾. According to the literature, prevention and early detection/diagnosis make it possible to effectively shorten the duration of delirium, minimizing its adverse effects⁽¹⁾.

With the growing number of studies on the subject, it becomes essential to conduct a review evaluating experimental and quasi-experimental studies on the effects of flexible visitation in the prevention and treatment of delirium in ICUs

METHOD

Study design

This systematic review protocol was developed in accordance with the guidelines established by the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) checklist⁽¹³⁾. In addition, the nine steps for conducting a systematic review were followed⁽¹⁴⁾, beginning with the formulation of the research question. Subsequently, the review

protocol is created and registered, which must include items 1 and 3 through 8. The third step involves defining the inclusion and exclusion criteria, followed by the development of the search strategy and the literature search to locate relevant studies. Next, the studies are selected and their quality assessed. After this phase, data extraction, synthesis of information, and analysis of the quality of the evidence are carried out. Finally, the findings are disseminated through publication, contributing to the dissemination of the conclusions obtained.

Step 1 - Formulation of the research question

This study will be conducted using the PICOS strategy (an acronym for Patient, Intervention, Control, Outcomes, and Study design), summarized in Table 1, to guide the formulation of the guiding question and eligibility criteria. Accordingly, the study was guided by the following research question: Is flexible visitation of ICU patients an effective intervention for the prevention and treatment of delirium?

Table 1 - Research question according to the PICOS strategy, Alfenas-MG, 2025

Population	Adult patients in Intensive Care Units (ICU)
Intervention	Flexible visitation
Control	Standard visitation or no visitation
Outcome	Prevention or treatment of delirium
Studies	Experimental and quasi-experimental studies

Source: Prepared by the authors, 2024; based on⁽¹⁵⁾.

Step 2 – Development and registration of the research protocol

The items described in Step 1 and in Steps 3 through 8 comprise the protocol, which was registered in the International Prospective Register of Systematic Reviews⁽¹⁶⁾, registration code CRD42024611387.

Step 3 - Definition of inclusion and exclusion criteria

This systematic review will include interventional studies (clinical trials and quasi-experiments), in any language and from any year, that use flexible visitation for the prevention and treatment of delirium in the ICU, whether as a stand-alone intervention or combined with other methods. The control group must receive conventional visitation or other non-pharmacological interventions for the prevention and treatment of delirium in intensive care.

There will be no restrictions regarding sex or ethnic origin of the participants. Studies involving adult critical care (individuals aged 18 years or older) will be considered. Exclusion criteria will include editorials, observational studies, and secondary studies such as reviews.

Step 4 - Development of the search strategy and literature search

The search for studies will be carried out in the following information sources: Cochrane Central Register of Controlled Trials (CENTRAL), Medical Literature Analysis and Retrieval System Online (MEDLINE) via

PubMed, EMBASE (via Embase.com), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Web of Science, Scopus, and Literatura Latino-Americana e do Caribe em Ciências da Saúde (LILACS).

The search strategy was developed by four authors with the contribution of a librarian experienced in health sciences. The bibliographic search was repeated immediately after the final analysis to allow for the review of newly published studies and their inclusion in this review.

Descriptors in Health Sciences (DeCS) in English, Spanish, and Portuguese were used in the LILACS database; Medical Subject Headings (MeSH) in CT.gov, CENTRAL, MEDLINE, Web of Science, Scopus, ReBEC, BDTD, and Google Scholar; Emtree terms in EMBASE; and Subject Headings in CINAHL. In addition to the thesauri of each database, keywords will also be considered to expand the search.

All terms relevant to this review (controlled and uncontrolled) will be combined in the databases using the Boolean operators AND and OR. Table 2 describes the terms that will be used in the MEDLINE search strategy based on MeSH.

Table 2 - Search strategy based on MeSH and keywords, Alfenas-MG, 2025.

Representation in the PICOS strategy	Terms	Block
Adult patients in Intensive Care Units (ICUs)	Critical Care* Care, Critical Intensive Care Care, Intensive Surgical Intensive Care Care, Surgical Intensive Intensive Care, Surgical Intensive Care Units* Intensive Care Unit Unit, Intensive Care ICU Intensive Care Units Adult Intensive Care Unit Intensive Support Intensive support Critical Illness* Critical Illnesses Critically Ill Illness, Critical Illnesses, Critical	A
Flexible visitation	Visitors to Patients* Visitors to Patient Patients' Visitors Patient Visitors Patient's Visitors Patients Visitors Patients' Visitor Visitor, Patients' Visitors, Patients' Caregivers* Caregiver Carers Carer Care Givers Care Giver Spouse Caregivers Caregiver, Spouse Caregivers, Spouse Spouse Caregiver Family Caregivers Caregiver Support Caregiver, Family Caregivers, Family Family Caregiver Informal Caregivers Caregiver, Informal Caregivers, Informal Informal Caregiver Flexible Family Visitation Involving Family And Friends In Care Family Presence Facilitation Non-Pharmacological Interventions Family presence Open visitation	B



	Visit Out Of Hours	
Prevention and treatment of delirium	Delirium* Intensive care unit delirium	C
Search strategy:	The controlled* and uncontrolled terms will be combined with OR, and subsequently, the blocks will be combined as follows: (A) AND (B) AND (C)	

Source: Prepared by the authors, 2024.

Legend: *Controlled term (MeSH).

The search strategy was adapted to the other databases after the completion of the MEDLINE search via PubMed.

Each selected article will undergo abstract and full-text reading. During the review, the reference lists of the included studies and systematic reviews will also be examined. In addition, unpublished and/or non-indexed studies

will be assessed, identified through sources such as ClinicalTrials.gov, the Brazilian Clinical Trials Registry (ReBEC), Google Scholar, and the Brazilian Digital Library of Theses and Dissertations (BDTD).

The search strategy was applied to the information sources, yielding a total of 6,609 studies, as shown in Table 3.

Table 3 - Search strategy based on MeSH and keywords, Alfenas-MG, 2025.

Source	Search strategy	Quantity
CENTRAL	"Critical Care" OR "Care, Critical" OR "Intensive Care" OR "Care, Intensive" OR "Surgical Intensive Care" OR "Care, Surgical Intensive" OR "Intensive Care Units" OR "Intensive Care Unit" OR "Unit, Intensive Care" OR "ICU Intensive Care Units" OR "Adult Intensive Care Unit" OR "Intensive Support" OR "Critical Illness" OR "Critical Illnesses" OR "Critically Ill" OR "Illness, Critical" OR "Illnesses, Critical" in All Text AND "Visitors to Patients" OR "Visitors to Patient" OR "Patients' Visitors" OR "Patient Visitors" OR "Patient's Visitors" OR "Patients Visitors" OR "Patients' Visitor" OR "Visitor, Patients" OR "Visitors, Patients" OR "Caregivers" OR "Caregiver" OR "Carers" OR "Carer" OR "Care Givers" OR "Care Giver" OR "Spouse Caregivers" OR "Caregiver, Spouse" OR "Caregivers, Spouse" OR "Spouse Caregiver" OR "Family Caregivers" OR "Caregiver Support" OR "Caregiver, Family" OR "Caregivers, Family" OR "Family Caregiver" OR "Informal Caregivers" OR "Caregiver, Informal" OR "Caregivers, Informal" OR "Informal Caregiver" OR "Flexible Family Visitation" OR "Involving Family And Friends In Care" OR "Family Presence Facilitation" OR "Non-Pharmacological Interventions" OR "Family presence" OR "Open visitation" OR "Visit Out Of Hours" in All Text AND "Delirium" OR "Intensive care unit delirium" in All Text - (Word variations have been searched)	72
MEDILINE/ PubMed	("Critical Care" OR "Care, Critical" OR "Intensive Care" OR "Care, Intensive" OR "Surgical Intensive Care" OR "Care, Surgical Intensive" OR "Intensive Care Units" OR "Intensive Care Unit" OR "Unit, Intensive Care" OR "ICU Intensive Care Units" OR "Adult Intensive Care Unit" OR "Intensive Support" OR "Critical Illness" OR "Critical Illnesses" OR "Critically Ill" OR "Illness, Critical" OR "Illnesses, Critical") AND ("Visitors to Patients" OR "Visitors to Patient" OR "Patients' Visitors" OR "Patient Visitors" OR "Patient's Visitors" OR "Patients Visitors" OR "Patients' Visitor" OR "Visitor, Patients" OR "Visitors, Patients" OR "Caregivers" OR "Caregiver" OR "Carers" OR "Carer" OR "Care Givers" OR "Care Giver" OR "Spouse Caregivers" OR "Caregiver, Spouse" OR "Caregivers,	240

	Spouse" OR "Spouse Caregiver" OR "Family Caregivers" OR "Caregiver Support" OR "Caregiver, Family" OR "Caregivers, Family" OR "Family Caregiver" OR "Informal Caregivers" OR "Caregiver, Informal" OR "Caregivers, Informal" OR "Informal Caregiver" OR "Flexible Family Visitation" OR "Involving Family And Friends In Care" OR "Family Presence Facilitation" OR "Non-Pharmacological Interventions" OR "Family presence" OR "Open visitation" OR "Visit Out Of Hours") AND ("Delirium" OR "Intensive care unit delirium")	
EMBASE	('intensive care'/exp OR 'intensive care' OR 'care, intensive'/exp OR 'care, intensive' OR 'critical care'/exp OR 'critical care' OR 'intensive therapy'/exp OR 'intensive therapy' OR 'therapy, intensive'/exp OR 'therapy, intensive' OR 'intensive care unit'/exp OR 'intensive care unit' OR 'intensive care units'/exp OR 'intensive care units' OR 'icu' OR 'icu's'/exp OR 'icu's' OR 'combined medical and surgical icu'/exp OR 'combined medical and surgical icu' OR 'combined surgical and medical icu'/exp OR 'combined surgical and medical icu' OR 'critical care unit'/exp OR 'critical care unit' OR 'intensive care department'/exp OR 'intensive care department' OR 'intensive therapy unit'/exp OR 'intensive therapy unit' OR 'intensive treatment unit'/exp OR 'intensive treatment unit' OR 'medical-surgery icu'/exp OR 'medical-surgery icu' OR 'medical/surgical icu'/exp OR 'medical/surgical icu' OR 'medical/surgical icus'/exp OR 'medical/surgical icus' OR 'medico-surgical icu'/exp OR 'medico-surgical icu' OR 'mixed medical and surgical icu'/exp OR 'mixed medical and surgical icu' OR 'mixed surgical and medical icu'/exp OR 'mixed surgical and medical icu' OR 'surgery/medical icu'/exp OR 'surgery/medical icu' OR 'surgical-medical icus'/exp OR 'surgical-medical icus' OR 'surgical/medical icu'/exp OR 'surgical/medical icu' OR 'unit, intensive care'/exp OR 'unit, intensive care') AND ('patient visitor' OR 'patient visitors' OR 'patient's visitor' OR 'patient's visitors' OR 'patients' visitor' OR 'visitors to patients' OR 'caregiver' OR 'care giver' OR 'caregivers' OR 'carer' OR 'carers' OR 'family caregiver' OR 'family caregivers' OR 'flexible family visitation' OR 'non-pharmacological interventions' OR 'family presence' OR 'open visitation') AND ('delirium' OR 'acute delirium' OR 'chronic delirium' OR 'delier' OR 'delire' OR 'deliria' OR 'delirious manifestation' OR 'delirious state' OR 'delirious syndrome' OR 'delirium acutum')	497
CINAHL	("Critical Care" OR "Care, Critical" OR "Intensive Care" OR "Care, Intensive" OR "Surgical Intensive Care" OR "Care, Surgical Intensive" OR "Intensive Care Units" OR "Intensive Care Unit" OR "Unit, Intensive Care" OR "ICU Intensive Care Units" OR "Adult Intensive Care Unit" OR "Intensive Support" OR "Critical Illness" OR "Critical Illnesses" OR "Critically Ill" OR "Illness, Critical" OR "Illnesses, Critical") AND ("Visitors to Patients" OR "Visitors to Patient" OR "Patients' Visitors" OR "Patient Visitors" OR "Patient's Visitors" OR "Patients Visitors" OR "Patients' Visitor" OR "Visitor, Patients" OR "Visitors, Patients" OR "Caregivers" OR "Caregiver" OR "Carers" OR "Carer" OR "Care Givers" OR "Care Giver" OR "Spouse Caregivers" OR "Caregiver, Spouse" OR "Caregivers, Spouse" OR "Spouse Caregiver" OR "Family Caregivers" OR "Caregiver Support" OR "Caregiver, Family" OR "Caregivers, Family" OR "Family Caregiver" OR "Informal Caregivers" OR "Caregiver, Informal" OR "Caregivers, Informal" OR "Informal Caregiver" OR "Flexible Family Visitation" OR "Involving Family And Friends In Care" OR "Family Presence Facilitation" OR "Non-Pharmacological Interventions" OR "Family presence" OR "Open visitation" OR "Visit Out Of Hours") AND ("Delirium" OR "Intensive care unit delirium")	533
Web of Science	"Critical Care" OR "Care, Critical" OR "Intensive Care" OR "Care, Intensive" OR "Surgical Intensive Care" OR "Care, Surgical Intensive" OR "Intensive Care Units" OR "Intensive Care Unit" OR	226



	"Unit, Intensive Care" OR "ICU Intensive Care Units" OR "Adult Intensive Care Unit" OR "Intensive Support" OR "Critical Illness" OR "Critical Illnesses" OR "Critically Ill" OR "Illness, Critical" OR "Illnesses, Critical" (All Fields) and "Visitors to Patients" OR "Visitors to Patient" OR "Patients' Visitors" OR "Patient Visitors" OR "Patient's Visitors" OR "Patients Visitors" OR "Patients' Visitor" OR "Visitor, Patients" OR "Visitors, Patients" OR "Caregivers" OR "Caregiver" OR "Carers" OR "Carer" OR "Care Givers" OR "Care Giver" OR "Spouse Caregivers" OR "Caregiver, Spouse" OR "Caregivers, Spouse" OR "Spouse Caregiver" OR "Family Caregivers" OR "Caregiver Support" OR "Caregiver, Family" OR "Caregivers, Family" OR "Family Caregiver" OR "Informal Caregivers" OR "Caregiver, Informal" OR "Caregivers, Informal" OR "Informal Caregiver" OR "Flexible Family Visitation" OR "Involving Family And Friends In Care" OR "Family Presence Facilitation" OR "Non-Pharmacological Interventions" OR "Family presence" OR "Open visitation" OR "Visit Out Of Hours" (All Fields) and "Delirium" OR "Intensive care unit delirium" (All Fields)	
Scopus	(ALL ("Critical Care" OR "Care, Critical" OR "Intensive Care" OR "Care, Intensive" OR "Surgical Intensive Care" OR "Care, Surgical Intensive" OR "Intensive Care Units" OR "Intensive Care Unit" OR "Unit, Intensive Care" OR "ICU Intensive Care Units" OR "Adult Intensive Care Unit" OR "Intensive Support" OR "Critical Illness" OR "Critical Illnesses" OR "Critically Ill" OR "Illness, Critical" OR "Illnesses, Critical") AND ALL ("Visitors to Patients" OR "Visitors to Patient" OR "Patients' Visitors" OR "Patient Visitors" OR "Patient's Visitors" OR "Patients Visitors" OR "Patients' Visitor" OR "Visitor, Patients" OR "Visitors, Patients" OR "Caregivers" OR "Caregiver" OR "Carers" OR "Carer" OR "Care Givers" OR "Care Giver" OR "Spouse Caregivers" OR "Caregiver, Spouse" OR "Caregivers, Spouse" OR "Spouse Caregiver" OR "Family Caregivers" OR "Caregiver Support" OR "Caregiver, Family" OR "Caregivers, Family" OR "Family Caregiver" OR "Informal Caregivers" OR "Caregiver, Informal" OR "Caregivers, Informal" OR "Informal Caregiver" OR "Flexible Family Visitation" OR "Involving Family And Friends In Care" OR "Family Presence Facilitation" OR "Non-Pharmacological Interventions" OR "Family presence" OR "Open visitation" OR "Visit Out Of Hours") AND ALL ("Delirium" OR "Intensive care unit delirium"))	4.815
LILACS Inglês	("Critical Care" OR "Care, Critical" OR "Intensive Care" OR "Care, Intensive" OR "Surgical Intensive Care" OR "Care, Surgical Intensive" OR "Intensive Care Units" OR "Intensive Care Unit" OR "Unit, Intensive Care" OR "ICU Intensive Care Units" OR "Adult Intensive Care Unit" OR "Intensive Support" OR "Critical Illness" OR "Critical Illnesses" OR "Critically Ill" OR "Illness, Critical" OR "Illnesses, Critical") AND ("Visitors to Patients" OR "Visitors to Patient" OR "Patients' Visitors" OR "Patient Visitors" OR "Patient's Visitors" OR "Patients Visitors" OR "Patients' Visitor" OR "Visitor, Patients" OR "Visitors, Patients" OR "Caregivers" OR "Caregiver" OR "Carers" OR "Carer" OR "Care Givers" OR "Care Giver" OR "Spouse Caregivers" OR "Caregiver, Spouse" OR "Caregivers, Spouse" OR "Spouse Caregiver" OR "Family Caregivers" OR "Caregiver Support" OR "Caregiver, Family" OR "Caregivers, Family" OR "Family Caregiver" OR "Informal Caregivers" OR "Caregiver, Informal" OR "Caregivers, Informal" OR "Informal Caregiver" OR "Flexible Family Visitation" OR "Involving Family And Friends In Care" OR "Family Presence Facilitation" OR "Non-Pharmacological Interventions" OR "Family presence" OR "Open visitation" OR "Visit Out Of Hours") AND ("Delirium" OR "Intensive care unit delirium")	



Português	("Cuidados Críticos" OR "Cuidados Intensivos" OR "Unidades de Cuidados Intensivos" OR "Unidade de Cuidados Intensivos" OR "Unidade de Terapia Intensiva" OR "UTI" OR "Unidade de Cuidados Intensivos para Adultos" OR "Suporte Intensivo" OR "Doença Crítica" OR "Doenças Críticas" OR "Doentes Críticos" OR "Doença Grave" OR "Doenças Graves") AND ("Visitantes de Pacientes" OR "Visitantes de Paciente" OR "Visitantes dos Pacientes" OR "Visitante de Pacientes" OR "Visitante do Paciente" OR "Visitantes de Pacientes Críticos" OR "Cuidadores" OR "Cuidador" OR "Cuidadores Informais" OR "Cuidador Familiar" OR "Apoio ao Cuidador" OR "Cuidador Conjugal" OR "Cuidadores Familiares" OR "Cuidador de Família" OR "Visitação Familiar Flexível" OR "Envolvimento da Família e Amigos no Cuidado" OR "Facilitação da Presença Familiar" OR "Intervenções Não-Farmacológicas" OR "Presença Familiar" OR "Visita Aberta" OR "Visita Fora do Horário") AND ("Delírio" OR "Delírio em Unidade de Terapia Intensiva")	2
Espanhol	("Cuidados Críticos" OR "Cuidados Intensivos" OR "Unidades de Cuidados Intensivos" OR "Unidad de Cuidados Intensivos" OR "Unidad de Terapia Intensiva" OR "UCI" OR "Unidad de Cuidados Intensivos para Adultos" OR "Soporte Intensivo" OR "Enfermedad Crítica" OR "Enfermedades Críticas" OR "Pacientes Críticos" OR "Enfermedad Grave" OR "Enfermedades Graves") AND ("Visitantes de Pacientes" OR "Visitantes de Paciente" OR "Visitantes de los Pacientes" OR "Visitante de Pacientes" OR "Visitante del Paciente" OR "Visitantes de Pacientes Críticos" OR "Cuidadores" OR "Cuidador" OR "Cuidadores Informales" OR "Cuidador Familiar" OR "Apoyo al Cuidador" OR "Cuidador Conyugal" OR "Cuidadores Familiares" OR "Cuidador de Familia" OR "Visita Familiar Flexible" OR "Involucrar a la Familia y Amigos en el Cuidado" OR "Facilitación de la Presencia Familiar" OR "Intervenciones No Farmacológicas" OR "Presencia Familiar" OR "Visita Abierta" OR "Visita Fuera del Horario") AND ("Delirio" OR "Delirio en Unidad de Terapia Intensiva")	2
CT.gov	("Critical Care" OR "Care, Critical" OR "Intensive Care" OR "Care, Intensive" OR "Surgical Intensive Care" OR "Care, Surgical Intensive" OR "Intensive Care Units" OR "Intensive Care Unit" OR "Unit, Intensive Care" OR "ICU Intensive Care Units" OR "Adult Intensive Care Unit" OR "Intensive Support" OR "Critical Illness" OR "Critical Illnesses" OR "Critically Ill" OR "Illness, Critical" OR "Illnesses, Critical") AND ("Visitors to Patients" OR "Visitors to Patient" OR "Patients' Visitors" OR "Patient Visitors" OR "Patient's Visitors" OR "Patients Visitors" OR "Patients' Visitor" OR "Visitor, Patients" OR "Visitors, Patients" OR "Caregivers" OR "Caregiver" OR "Carers" OR "Carer" OR "Care Givers" OR "Care Giver" OR "Spouse Caregivers" OR "Caregiver, Spouse" OR "Caregivers, Spouse" OR "Spouse Caregiver" OR "Family Caregivers" OR "Caregiver Support" OR "Caregiver, Family" OR "Caregivers, Family" OR "Family Caregiver" OR "Informal Caregivers" OR "Caregiver, Informal" OR "Caregivers, Informal" OR "Informal Caregiver" OR "Flexible Family Visitation" OR "Involving Family And Friends In Care" OR "Family Presence Facilitation" OR "Non-Pharmacological Interventions" OR "Family presence" OR "Open visitation" OR "Visit Out Of Hours") AND ("Delirium" OR "Intensive care unit delirium")	60
ReBEC	"Delirium" AND "Intensive Care Unit"	7
BDTD	(Todos os campos:"Critical Care" OR "Care, Critical" OR "Intensive Care" OR "Care, Intensive" OR "Surgical Intensive Care" OR "Care, Surgical Intensive" OR "Intensive Care Units" OR "Intensive Care Unit" OR "Unit, Intensive Care" OR "ICU Intensive Care Units" OR "Adult Intensive Care Unit" OR "Intensive Support" OR "Critical Illness" OR "Critical Illnesses" OR	51



	"Critically Ill" OR "Illness, Critical" OR "Illnesses, Critical" E Todos os campos:"Visitors to Patients" OR "Visitors to Patient" OR "Patients' Visitors" OR "Patient Visitors" OR "Patient's Visitors" OR "Patients Visitors" OR "Patients' Visitor" OR "Visitor, Patients"" OR "Visitors, Patients"" OR "Caregivers" OR "Caregiver" OR "Carers" OR "Carer" OR "Care Givers" OR "Care Giver" OR "Spouse Caregivers" OR "Caregiver, Spouse" OR "Caregivers, Spouse" OR "Spouse Caregiver" OR "Family Caregivers" OR "Caregiver Support" OR "Caregiver, Family" OR "Caregivers, Family" OR "Family Caregiver" OR "Informal Caregivers" OR "Caregiver, Informal" OR "Caregivers, Informal" OR "Informal Caregiver" OR "Flexible Family Visitation" OR "Involving Family And Friends In Care" OR "Family Presence Facilitation" OR "Non-Pharmacological Interventions" OR "Family presence" OR "Open visitation" OR "Visit Out Of Hours" E Todos os campos:"Delirium" OR "Intensive care unit delirium")	
Google Scholar	("Critical Care" OR "Intensive Care Units" OR "Critical Illness") AND ("Visitors to Patients" OR "Flexible Family Visitation") AND Delirium	100 primeiros (322)

Source: Prepared by the authors, 2024.

Step 5 - Study selection

The search will be conducted in the aforementioned information sources, and the results will be imported into the Rayyan web application, where duplicate studies will be identified and removed. After eliminating duplicates, the article selection process will take place based on titles and abstracts, through blinded collaboration between the reviewers.

In Rayyan, study selection will occur in two stages. In the first, titles and abstracts will be carefully examined in light of the predefined eligibility criteria. This initial screening will allow the identification of the most promising articles, which will then be further analyzed in the next stage⁽¹⁷⁾.

The preselected articles from the previous stage will be read in full. This thorough reading aims to confirm whether the articles truly meet the eligibility criteria and whether they contribute significantly to the research topic.

In both stages, two reviewers will independently assess each article. If disagreement arises between them, a third reviewer will be consulted to conduct a new analysis of the article. Subsequently, all researchers will meet to discuss the different opinions and reach a consensus on whether to include or exclude the article.

Step 6 - Quality assessment of the studies

The primary outcome of the study is the prevention and treatment of delirium, which will be evaluated using validated instruments such as the Confusion Assessment Method for Intensive Care Units (CAM-ICU), among others⁽¹⁸⁾. The outcome will be assessed based on the results reported by the studies before and after the intervention.

The Cochrane Risk of Bias (ROB) 2.0 tool and the ROBINS-I tool will be used in this study to assess the risk of bias, with the former applied to randomized clinical trials (parallel,

cluster, and crossover controlled trials)⁽¹⁹⁾, and the latter applied to quasi-experimental or non-randomized studies⁽²⁰⁾.

To ensure impartiality and rigor in the process, two researchers will independently evaluate the risk of bias. In case of disagreements between evaluations, a third

researcher will be called upon to mediate a discussion and reach a final consensus.

Step 7 -Data extraction

Two researchers will independently extract data from the included studies using a form designed by the authors. The components of this form are presented in Table 3 below.

Table 4 - Information to be extracted from the selected articles, Alfenas-MG, 2025

Method	Study Identification	Author(s) Year of publication Country of study Language
	Participants	Eligibility criteria Clinical condition
	Setting	ICU classification by clinical type ICU details
	Design and Group Allocation	Study design Study duration Follow-up groups (experimental group × control/placebo group) Randomization Allocation concealment
	Intervention (Flexible Visitation)	Duration of visits Frequency of visits Duration of the study
	Control Group	Type of control (no treatment, standard treatment, placebo) Description of the intervention
	Primary Outcome	Assessment instrument used Measurement time points
	Other Outcomes	Name and definition Assessment instrument used Measurement time points
	Results	Number of participants randomized or allocated per group analyzed Description of dropout participants Demographic data of each group Group summary data at different assessment time points Adverse events Effect of the intervention
	Discussion	Interpretation of results Extent of generalizability Suggestions for future studies Study limitations

Conclusion

Main conclusions

Source: Prepared by the authors, 2024.

The researchers involved in this review may contact the authors of the included studies by e-mail to obtain additional information, if necessary.

8 - Data synthesis and quality assessment of the evidence

Depending on the results obtained in this review, the data may be analyzed quantitatively, through meta-analysis, and/or qualitatively, through narrative synthesis.

If meta-analysis is feasible, the data will be processed using the Stata statistical software. The risk ratio will be used for dichotomous variables and the mean difference for continuous variables, both with a 95% confidence interval and a 5% significance level.

Heterogeneity among studies will be assessed using Cochran's Q statistic⁽²¹⁾ and Higgins' I² statistic⁽²²⁾, with I² values of 25%, 50%, and 75% indicating low, moderate, and high heterogeneity, respectively. The results will be presented in a forest plot.

If necessary, a subgroup analysis may be performed to explore potential sources of heterogeneity, such as type of intervention, control group, age groups, treatment duration, and study quality.

The quality of the evidence will be assessed using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) system⁽²³⁾. This

assessment will be conducted by two researchers independently to ensure impartiality and rigor. In case of disagreements, a third researcher will be invited to participate in a joint meeting to reach consensus.

Step 9 - Publication and dissemination of results

After the completion of these stages, the systematic review article will be written with clear and objective language, describing in detail each phase carried out, from the selection of the title to the presentation of the conclusions.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

REFERENCES

1. Al-Hoodar RK, Lazarus ER, Omari OA, Zaabi OA. Incidence, associated factors, and outcome of delirium among patients admitted to ICUs in Oman. *Crit Care Res Pract*. 2022;2022(1):4692483. Doi: <https://doi.org/10.1155/2022/4692483>
2. Teixeira AKS, Nascimento TS, Sousa ITL, Sampaio LRL, Pinheiro ARM. Incidência de lesão por pressão em Unidades de Terapia Intensiva em hospital com acreditação. *Estima* (Online). 2017;15(3):152-60. <https://doi.org/10.5327/Z1806-3144201700030006>
3. Vasconcelos JMB, Caliri MHL. Nursing actions before and after a protocol for preventing pressure injury in intensive care. *Esc Anna Nery*. 2017;21. Doi: <https://doi.org/10.5935/1414-8145.20170001>



4. Souza TL, Azzolin KO, Fernandes VRC. Cuidados multiprofissionais para pacientes em delirium em terapia intensiva: revisão integrativa. *Rev Gaúcha Enferm.* 2018;39. Doi: <https://doi.org/10.1590/1983-1447.2018.2017-0157>
5. Leslie DL, Inouye SK. The importance of delirium: economic and societal costs. *J Am Geriatr Soc.* 2011;59:S241-S243. Doi: <https://doi.org/10.1111/j.1532-5415.2011.03671.x>
6. Collinsworth AW, Priest EL, Campbell CR, Vasilevskis EE, Masica AL. A review of multifaceted care approaches for the prevention and mitigation of delirium in intensive care units. *J Intensive Care Med.* 2016;31(2):127-41. Doi: <https://doi.org/10.1177/0885066614553925>
7. Vasilevskis EE, Chandrasekhar R, Holtze CH, Graves J, Speroff T, Girard TD, Patel MB, Hughes CG, Cao A, Pandharipande PP, Ely EW. The cost of ICU delirium and coma in the intensive care unit patient. *Med Care.* 2018;56(10):890-7. Doi: <https://doi.org/10.1097/mlr.0000000000000975>
8. Salluh JIF, Wang H, Schneider EB, Nagaraja N, Yenokyan G, Damluji A, Serafim RB, Stevens RD. Outcome of delirium in critically ill patients: systematic review and meta-analysis. *BMJ.* 2015;350:h2538. Doi: <https://doi.org/10.1136/bmj.h2538>
9. Tang B, Wang XT, Chen WJ, Zhu SH, Chao YG, Zhu B, He W, Wang B, Cao FF, Liu YJ, Fan XJ. Experts consensus on the management of delirium in critically ill patients. *Zhonghua Nei Ke Za Zhi.* 2019 Feb 1;58(2):108-18. Doi: <https://doi.org/10.3760/cma.j.issn.0578-1426.2019.02.007>
10. Mehrnejad N, Ganji T, Ardesliri M, Fathi P. The effect of family presence at the bedside on serum cortisol levels and physiological indexes in patients hospitalized in intensive care unit. *Iranian Journal of Cardiovascular Nursing.* 2014 Mar 10;2(4):36-42. Available from: <http://journal.icns.org.ir/article-1-155-en.html>
11. Rosa RG, Tonietto TF, da Silva DB, Gutierrez FA, Ascoli AM, Madeira LC, Rutzen W, Falavigna M, Robinson CC, Salluh JI, Cavalcanti AB. Effectiveness and safety of an extended ICU visitation model for delirium prevention: a before and after study. *Critical Care Medicine.* 2017 Oct 1;45(10):1660-7. Doi: <https://doi.org/10.1097/CCM.0000000000002588>
12. Marra A, Ely EW, Pandharipande PP, Patel MB. The ABCDEF bundle in critical care. *Critical care clinics.* 2017 Apr 1;33(2):225-43. Doi: <https://doi.org/10.1016/j.ccc.2016.12.005>
13. Moher D, Stewart L, Shekelle P. Implementing PRISMA-P: recommendations for prospective authors. *Systematic reviews.* 2016 Dec;5:1-2. Doi: <https://doi.org/10.1186/s13643-016-0191-y>
14. Donato H, Donato M. Stages for undertaking a systematic review. *Acta Med Port.* 2019;32(3):227-35. Doi: <https://doi.org/10.20344/amp.11923>
15. Araújo WCO. Recuperação da informação em saúde: construção, modelos e estratégias. *ConCI: Convergências em Ciência da Informação.* 2020;3(2):100-34. Doi: <https://doi.org/10.33467/conci.v3i2.13447>
16. International Prospective Register Of Systematic Reviews - PROSPERO. National Institute for Health Research (NIHR). 2024. Available from: <https://www.crd.york.ac.uk/prospERO/>
17. Ouzzani M, Hammady H, Fedorowicz Z, Elmagarmid A. Rayyan—a web and mobile app for systematic reviews. *Systematic reviews.* 2016 Dec;5:1-0. Doi: <https://doi.org/10.1186/s13643-016-0384-4>
18. Hartmann SP, Wagner GP. Instrumentos de avaliação do delirium em unidades de terapia intensiva: uma revisão sistemática da literatura. *Psicol Hosp.* 2015;13(1):02-18. Available from: https://pepsic.bvsalud.org/scielo.php?script=sci_abstract&pid=S1677-74092015000100002
19. Sterne JA, Savović J, Page MJ, Elbers RG, Blencowe NS, Boutron I, Cates CJ, Cheng



HY, Corbett MS, Eldridge SM, Emberson JR. RoB 2: a revised tool for assessing risk of bias in randomised trials. *bmj*. 2019 Aug 28;366. Doi: <https://doi.org/10.1136/bmj.l4898>

20. Sterne JA, Hernán MA, McAleenan A, Reeves BC, Higgins JP. Assessing risk of bias in a non-randomized study. In: *Cochrane handbook for systematic reviews of interventions*. 2019. p. 621-641. Available from: <https://training.cochrane.org/handbook/archive/v6.4/chapter-25>

21. Lau J, Ioannidis JPA, Schmid CH. Quantitative synthesis in systematic reviews. *Ann Intern Med*. 1997;127(9):820-26. Doi: <https://doi.org/10.7326/0003-4819-127-9-199711010-00008>

22. Higgins JPT, Thompson SG. Quantifying heterogeneity in a meta-analysis. *Stat Med*. 2002;21(11):1539-58. <https://doi.org/10.1002/sim.1186>

23. Bezerra CT, Grande AJ, Galvão VK, Santos DH, Atallah ÁN, Silva V. Assessment of the strength of recommendation and quality of evidence: GRADE checklist. A descriptive study. *Sao Paulo Medical J*. 2022 Sep 12;140(6):829-36. Doi: <https://doi.org/10.1590/1516-3180.2022.0043.R1.07042022>

Funding and Acknowledgments:

This work was supported by the Coordination for the Improvement of Higher Education Personnel - Brazil (CAPES) - Funding Code 001.

Declaration of Conflict of Interest:

Nothing to declare

Author Contributions

Roberta Garcia Gomes. Creator, executor, developer, responsible for the initial writing of the protocol and approval of the final version.

João Vitor Andrade. Executor, developer, responsible for the initial writing of the protocol and approval of the final version.

Mariane Inaraí Alves. Executor, developer, responsible for the initial writing of the protocol and approval of the final version.

Juliana Cristina Martins de Souza. Executor, developer, responsible for the initial writing of the protocol and approval of the final version.

Priscila Yoshida Machado Ferreira. Executor, developer, responsible for the initial writing of the protocol and approval of the final version.

Patrícia Scotini Freitas. Responsible for monitoring, in addition to reading and approving the final version.

Namie Okino Sawada. Responsible for monitoring, in addition to reading and approving the final version.

Scientific Editor: Francisco Mayron Morais Soares. Orcid: <https://orcid.org/0000-0001-7316-2519>